

SPRING

## CME SECTION

**Community Based HIV  
Treatment Adherence Support;  
NJ Standards of Practice***Paula Toynton, M.Ed*

2

## ARTICLES

**New York City HIV Superbug:  
Fear or Fear Not?***Stephen M Smith*

13

**Non-Occupational Post-  
Exposure Prophylaxis***Kimi Nakata, MSW, MPH*

17

## FEATURES

**Director's Message***Dion Richetti, DC*

1

**Publisher's Box**

15

**In the News***Guidelines for the Use of  
Antiretroviral Agents in HIV-1-  
Infected Adults and Adolescents  
(updated)*

16

*FDA WARNING on Rifampin-  
Ritonavir*

16

**Internet Resources**

19

**SAVE  
THE DATE!****Reducing Perinatal HIV  
Transmission***November 3, 2005: Princeton***New Jersey Ryan White  
All-Titles conference***November 15, 2005: Piscataway**See back cover for more information**New Jersey*  
**AIDS**LINEVolume 1 Number 4  
Spring 2005**Director's Message****MAKING LEMONADE:****THE 2005 NEW JERSEY RYAN WHITE ALL-TITLES CONFERENCE**

Some expressions, no matter how overused, are just appropriate. As I watch the HIV/AIDS epidemic in the US, one particular expression keeps coming to mind: when life hands you lemons, make lemonade. Healthcare services for people with HIV/AIDS represent a thirst that will not be quenched. Regardless of what's in our "cupboard", we will need to have services and medicine available. The idea is that we must make something that is good from what is at hand.

Since 1999 the New Jersey Department of Health and Senior Services and UMDNJ have sponsored a biannual Ryan White CARE Act All Titles Conference. The conference is a gathering of providers and consumers, many of whom have spent the better part of the last two decades responding to the emergency of the AIDS crisis. This event draws two hundred people from throughout New Jersey, and is an opportunity to get a good sense of the "state of the state" around HIV issues. It is developed and planned by the Statewide Coordinated Statement of Need Planning Task Force. This year's program will take place on November 15, 2005 at the Rutgers University Busch Campus Center in Piscataway.

The current Ryan White CARE act expires on September 30, 2005. Arriving on the heels of (what we hope will be) a reauthorized Ryan White CARE Act, this year's conference will be for many of us, a vital transitional conversation. As the nation wrestles with the costs of caring for an increasing number of people living with HIV, and the availability of HIV specific domestic funds remains flat, this conference will center on making lemonade: doing the best we can

with the resources available. Like it or not, the appropriations to this act are unlikely to increase. The conference presentations and discussions will focus on recognizing the challenges faced by everyone working to support the 32,000+ New Jerseyans we know are living with the virus, and practical solutions to supporting them in a changing environment.

Participants at the conference will hear from both local and national leaders in HIV/AIDS on the implications of looking at HIV through the lens of a chronic disease model. Workshops on the availability of Non-Ryan White resources will be held in five topic areas.

One of the most compelling aspects of the conference is the All-Titles Discussion. This section breaks the conference participants up into groups by the title with which they have the most interest or involvement.<sup>1</sup> Providers and consumers of HIV services funded by each of the titles have the opportunity to participate in a substantive, facilitated discussion. These discussions are recorded and incorporated into a portion of the next Statewide Coordinated Statement of Need.

At this point, all that we can be sure of in regards to resources for our clients living with HIV is that there will be changes. In preparation for change, it is important that people who care about the HIV epidemic let their representatives in congress know what is needed. Regardless of how things move on the political front, the work will go on, more people will be infected, and more people will need help. Come to Piscataway in November to be part of the solution.

**Dion Richetti, DC**Director, Division of AIDS Education  
UMDNJ - Center for Continuing and Outreach Education<sup>1</sup>. Reference note on page 9**Register** for the New Jersey  
Ryan White All-Titles  
conference online at [www.pware.com/646a](http://www.pware.com/646a).

## COMMUNITY BASED HIV TREATMENT ADHERENCE SUPPORT; NEW JERSEY STANDARDS OF PRACTICE

### TARGET AUDIENCE

This activity is designed for physicians and nurses, and for other health care professionals who are involved in the care and support of individuals with HIV infection.

### STATEMENT OF NEED:

Effective treatment of HIV infection and AIDS is based on continuous monitoring and use of antiretroviral medications, which are often associated with complex regimens and unpleasant side effects. The U.S. Dept. of Health and Human Services issued a supplement on Treatment Adherence to accompany the *Guidelines for the Use of Antiretroviral Agents in HIV-Infected Adults and Adolescents* (October 29, 2004), which were summarized in the last issue of New Jersey AIDSline. This supplement, *Adherence to Potent Antiretroviral Therapy October 29, 2004*, is available at [http://www.aidsinfo.nih.gov/guidelines/adult%5CAH\\_102904.pdf](http://www.aidsinfo.nih.gov/guidelines/adult%5CAH_102904.pdf). In the document, a national panel of experts on HIV/AIDS treatment and treatment adherence concluded that "Suboptimal adherence is common. Surveys have determined that one third of patients missed doses within 3 days of the survey." They note that antiretroviral treatment is associated with effective suppression of viral (HIV) activity only when it is consistently taken, and that "suboptimal adherence has been reported to decrease virologic control and has been associated with increased morbidity and mortality." To provide effective HIV/AIDS treatment that will meet the standards of care set by federal and professional guidelines, clinicians and other health care and HIV support service professionals need to understand and develop strategies to promote and support treatment adherence.

### LEARNING OBJECTIVES

Upon the completion of this activity, participants should be able to:

- **Explain** the roles of the patient, the clinician, the health care program, and the regimen in supporting or creating obstacles to adherence.
- **Recognize** reliable and unreliable predictors of adherence
- **Identify** strategies to improve treatment adherence that are related to each element of treatment adherence

### METHOD OF INSTRUCTION:

Participants should read the learning objectives and review the activity in its entirety. After reviewing the material, complete the self-assessment test consisting of a series of multiple-choice questions. Upon completing this activity as designed and achieving a passing score of 70% or more on the self-assessment test, participants will receive a CME credit letter awarding AMA/PRA category 1 credit and the test answer key six (6) weeks after receipt of the

self-assessment test, registration, and evaluation materials.

Estimated time to complete this activity as designed is 1 hour.

UMDNJ-Center for Continuing and Outreach Education is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

UMDNJ-Center for Continuing and Outreach Education designates this educational activity for a maximum of 1 category 1 credit toward the AMA Physician's Recognition Award. Each physician should claim only those credits that he/she actually spent in the activity.

The activity was prepared in accordance with the ACCME Essentials.

This activity was reviewed for relevance, accuracy of content, balance of presentation, and time required for participation by Dion Richetti, DC, Patricia Kloser, MD, MPH, and Debbie M. Winters, MSN, CNS, ACRN.

### FACULTY:

Paula Toynton, M.Ed., is Senior Director of Education, Prevention and Advocacy, at Hyacinth AIDS Foundation in New Jersey.

### DISCLOSURE:

In accordance with the disclosure policies of UMDNJ and to conform with ACCME and FDA guidelines, all program faculty are required to disclose to the activity participants: 1) the existence of any financial interest or other relationships with the manufacturers of any commercial products/devices, or providers of commercial services, that relate to the content of their presentation/material, or the commercial contributors of this activity, that could be perceived as a real or apparent conflict of interest; and 2) the identification of a commercial product/device that is unlabeled for use or an investigational use of a product/ device not yet approved.

### FACULTY DISCLOSURE DECLARATIONS:

The faculty listed below declare that they have no financial relationships with any corporate organization whose product(s) will be discussed in this presentation:

Paula Toynton, M.Ed

Patricia Kloser, MD, MPH (Field Tester)

Debbie M. Winters, MSN, CNS, ACRN (Field Tester)

### OFF-LABEL USAGE DISCLOSURE:

This activity does not contain information of commercial products/devices that are unlabeled for use or investigational uses of products not yet approved.

### DISCLAIMER:

The views expressed in this activity are those of the faculty. It should not be inferred or assumed that they are expressing the views of NJDHSS-

Division of HIV/AIDS Services, UMDNJ, or any manufacturer of pharmaceuticals.

This activity does not describe drug selection and dosage. Participants are urged to consult the full prescribing information on any agent(s) presented in this activity for recommended dosage, indications, contraindications, warnings, precautions, and adverse effects before prescribing any medication. This is particularly important when a drug is new or infrequently prescribed.

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### GRANTOR ACKNOWLEDGEMENT

This activity is supported by an educational grant from NJDHSS Division of HIV/AIDS Services through a MOA titled, "Education and Training for Physicians and other Healthcare Professionals in the Diagnosis and Treatment of HIV/AIDS."

## NURSES

UMDNJ-CCOE has applied for nursing continuing education credit for this activity and anticipates that it will be available beginning July 15, 2005, online at

<http://ccoe.umdnl.edu/aids>

# HIV TREATMENT ADHERENCE

## PART I:

## USDHSS SUPPLEMENT ON HIV TREATMENT ADHERENCE

### ADHERENCE TO POTENT ANTIRETROVIRAL THERAPY (USDHHS, OCTOBER 29, 2004)

#### RECOMMENDATIONS

The USDHHS publishes HIV care and treatment guidelines, which are updated frequently to reflect new research findings and recommend the use of best practices for care of individuals with HIV infection and AIDS. This adherence supplement, published at the same time as *Guidelines for the Use of Antiretroviral Agents in HIV-Infected Adults and Adolescents* (summarized in the last issue of New Jersey AIDSline), is available online at [http://www.aidsinfo.nih.gov/guidelines/adult%5CAH\\_102904.pdf](http://www.aidsinfo.nih.gov/guidelines/adult%5CAH_102904.pdf). The antiretroviral guidelines were again updated on April 07, 2005 (see notes in "In the News" section).

The Adherence supplement to the November 2004 Antiretroviral Therapy Guidelines summarizes current research findings and questions about barriers to treatment adherence, as well as areas of potential effective intervention to improve treatment adherence. The New Jersey Guidelines summarized in this article, based on the collaboration of providers and consumers, have a very similar approach to identifying working to reduce barriers, and improving linkages to provide a network of formal and informal treatment adherence support. The USDHHS supplement also identifies predictors of adherence and non-adherence, noting that even among patients who are homeless, clinics can adjust their practices to strengthen the relationship of the clinic and staff to patients. The panel cautions clinicians and researchers that new technology aids to measuring adherence have not proven more accurate than clinician and patient predictions or estimates of treatment adherence.

This brief (5 pages) supplement to the Guidelines for the Use of Antiretroviral Agents in HIV-Infected Adults and Adolescents is a valuable summary of recent research and offers a great deal of practical guidance for the clinician and interdisciplinary team seeking to work with patients to make treatment adherence more possible and common, and to improve treatment outcomes for all patients.

#### PREDICTORS OF ADHERENCE

Predictors of **optimal adherence** to HIV medications, and hence, optimal viral suppression, include

- 1) availability of emotional and practical life supports,
- 2) a patient's ability to fit medications into his or her daily routine,
- 3) understanding that suboptimal adherence leads to resistance,
- 4) recognizing that taking all medication doses is critical,
- 5) feeling comfortable taking medications in front of others and
- 6) keeping clinic appointments.

Predictors of **inadequate adherence** to HIV medications found in this research included:

- 1) lack of trust between clinician and patient,
- 2) active drug and alcohol use,
- 3) active mental illness (e.g., depression),
- 4) lack of patient education and inability of patients to identify their medications, and
- 5) lack of reliable access to primary medical care or medication.

Other sources of instability influencing adherence include domestic violence and discrimination. Medication side effects can also cause inadequate adherence as can fear of or experiencing metabolic and morphologic side effects of HAART.

#### CONCLUSIONS

**Patient related strategies:** Selected factors (e.g., sex, race, low socioeconomic status or education level, and past drug use) are not reliable predictors of suboptimal adherence. Conversely, higher socioeconomic status and education level and a lack of past drug abuse do not predict optimal adherence. No patient should automatically be excluded from antiretroviral therapy simply because he or she exhibits a behavior or characteristic judged by the clinician to indicate a likelihood of nonadherence.

**Regimen-related strategies:** Regimens should be simplified as much as possible by reducing the number of pills and therapy frequency and by minimizing drug interactions and side effects. For certain patients, problems with complex regimens are of lesser

importance, but evidence supports simplified regimens with reduced pill numbers and dose frequencies. With the effective options for initial therapy noted in this report and the observed benefit of less frequent dosing, twice-daily dosing of HAART regimens is feasible for the majority of patients.

### ADDITIONAL RESOURCES

HIV InSite:

<http://hivinsite.ucsf.edu/InSite?page=kb-03-02-09#S4X>

Knowledge Base Chapter: *Adherence to HIV Antiretroviral Therapy*, May 2005, Edward L. Machtinger, MD and David R. Bangsberg, MD (both University of California - San Francisco).

*Predictors of Adherence* summarizes the findings of international HIV treatment adherence studies, including focus on patient characteristics, treatment regimen factors, disease characteristics, the patient-provider relationship, and the clinical setting, with hyperlinked references.

## HIV TREATMENT ADHERENCE

### PART II:

## NEW JERSEY STANDARDS OF PRACTICE FOR COMMUNITY BASED HIV TREATMENT ADHERENCE

*Paula Toynton, M.Ed., Senior Director of Education, Prevention and Advocacy, Hyacinth AIDS Foundation [document in review for adoption by the New Jersey Dept. of Health and Senior Services, Division of HIV/AIDS Services]*

### LEARNING OBJECTIVES:

- **Explain** the roles of the patient, the clinician, the health care program, and the regimen in supporting or creating obstacles to adherence.
- **Recognize** reliable and unreliable predictors of adherence
- **Identify** strategies to improve treatment adherence that are related to each element of treatment adherence



### HIV DISEASE AND TREATMENT

HIV disease management and treatment, includes four basic protocols: antiretroviral therapy (ART) to inhibit viral replication and slow disease progression; prophylactic drug therapy to prevent the occurrence or reoccurrence of opportunistic infections when the immune system is significantly compromised; treatment of opportunistic infections when they occur; and complementary and alternative medicine (CAM) to enhance immune system function and manage side effects and overall health. The federal Department of Health and Human Services (DHHS) publishes a set of guidelines for HIV disease management<sup>1</sup>. These guidelines are updated frequently to reflect advances in ART and other research outcomes of HIV treatment.

### ADHERENCE

While no exact level of adherence needed for viral suppression has yet been determined, research indicates that at minimum 95% adherence is required and to be sure, 100% adherence is recommended. Even a small decrease in adherence can greatly increase viral load. If the virus is allowed to mutate into drug resistant strains, the treatment regimen can become ineffective, which reduces treatment options for individuals and partners they may infect with these strains<sup>2</sup>. This required level of adherence makes antiretroviral treatment regimens quite demanding. The price of not achieving strict adherence is consequently quite high and includes viral break through, limited future treatment options, and poor health outcomes, similar to those expected before 1996.

### RECOMMENDATIONS FOR COMMUNITY BASED ADHERENCE SUPPORT PROGRAM GOALS

The goals of clinic and social service based adherence support programs are to increase the proportion of people living with HIV who are linked to appropriate care and treatment services, including care for co-morbidities, who understand and actively participate in their medical care and remain adherent to treatment regimens. Through collaboration, both clinical and social services provide community based adherence support.

### STANDARDS RECOMMENDATIONS

The "New Jersey Standards of Practice for HIV Treatment Adherence Support" for community based social service adherence support interventions include six programmatic areas, identified by the literature and research on HIV adherence factors. They include: staffing and methodologies for an interdisciplinary approach to



services; outreach and referral activities; program characteristics; client environmental and social factors; client psychological and personality factors; and client educational programs.

### **STANDARD 1. STAFFING AND METHODS FOR AN INTERDISCIPLINARY APPROACH**

Patients with HIV, like others with chronic illness, benefit from interdisciplinary care. Collaboration between physicians, AIDS service organizations, and other community-based organizations can address inclusively, the medical, social, psychological, educational, and spiritual dimensions of living with HIV disease. The following are recommendations for community based adherence program staffing and methods that will effectively support an interdisciplinary approach to adherence.

#### **STANDARD 1.1: REGIONAL AND AGENCY STAFFING**

- A. All staff working with HIV positive clients should be able to do a basic assessment of clients' health outcomes and access and adherence to medical care to assess client need for treatment adherence counseling services.
- B. HIV regional service networks should be funded to provide one treatment adherence counselor for every 75 clients in need of adherence support (those marginally in care, not in care, or struggling with medication adherence).
- C. The agency may address staff need for psychosocial support.

#### **STANDARD 1.2: TREATMENT ADHERENCE STAFF MUST MEET CORE PROFESSIONAL COMPETENCY REQUIREMENTS IDENTIFIED BY THE NATIONAL TREATMENT EDUCATION PROJECT<sup>3</sup>.**

Effective treatment adherence staff should be able to:

- A. Articulate the minimum requirement for establishing "unmet need" to ensure that the client is accessing primary medical care;
- B. Demonstrate knowledge of basic HIV disease and treatment;
- C. Teach clients HIV information and assist to develop skills necessary to obtain comprehensive care;
- D. Access credible information and resources for person's living with HIV in highly impacted and emerging epicenters. (Internet, newsletters, hotlines, government);
- E. Use culturally sensitive and client-centered education and support strategies;
- F. Work with patients/clients to identify their treatment access and information needs, set goals and create and implement a service plan.

### **STANDARD 1.3: OUTCOMES AND MEASURES FOR STAFFING AND METHODS**

The effectiveness of the treatment adherence staffing is measured by:

- A. Treatment adherence counselor's demonstrated proficiency of the above competencies;
- B. All staff's ability to assess client need for treatment adherence support;
- C. Treatment adherence counselor's ability to collaborate with both clinical and community based program staff as part of outreach and identification of clients marginally or not in care and as part of the client's treatment adherence service plan;
- D. The percentage of clients retained in treatment adherence counseling;
- E. The percent of clients who are in care as defined by HRSA.

### **STANDARD 2. PROGRAM CHARACTERISTICS:**

HIV clinical programs should be committed to accessible, continuous, comprehensive, Client-centered, and prevention-oriented care. The clinical setting should make it possible for clients to adhere to their medications and the demands of the entire clinical regimen. This can be done entirely within the clinic or in collaboration with other community based resources. The following are recommendations for ways in which community based social service organizations can support and complement clinical programs.

#### **STANDARD 2.1: PROGRAMS ARE BASED ON AN INTERDISCIPLINARY APPROACH**

To ensure an effective interdisciplinary approach to client care, written methodologies and collaborations should exist between agencies and clinics, and within agencies and clinics between departments, which clearly delineate and coordinate roles and responsibilities of health and social service providers to optimize adherence and health outcomes.

#### **STANDARD 2.2: INTERVENTION STRATEGIES**

Strategies and methodologies should meet diverse population needs. Some special populations include: women, IDUs, offenders and ex-offenders re-entering the community, men-who-have-sex-with men (MSM), youth, African American, Latino, and transgendered individuals.

#### **STANDARD 2.3: PROGRAM ELEMENTS**

- A. All people living with HIV have health outcome assessments (CD4+, Viral Load, ART) completed every six months and referrals to treatment adherence support are made as needed.

- B. HIV treatment adherence services are located in areas of high prevalence.
- C. A thorough assessment of all clients' medical outcomes and treatment access and adherence needs is conducted every six months. Health outcome assessments should take into account co-morbid conditions such as hepatitis, gynecological and dental care, nutritional needs, addiction and mental health needs, as well as secondary prevention.
- D. All staff are trained to maintain strict confidentiality of clients' diagnoses, including route of HIV exposure.
- E. Services are culturally competent and offered in the dominant language(s) of the population.
- F. Client environmental factors and educational needs are a standard part of the assessment and referrals are made to appropriate social service programs.
- G. Clients are linked with health care and community resources that address medical care, mental health and addiction services, and basic needs such as food, clothing, and housing.
- H. Flexible treatment counseling appointments, including evening hours and home visits are provided.
- I. Communication between clients and their health care providers, families, spouses, companions, or housemates is facilitated to allow for best adherence to care and medication taking.
- J. Clients assisted in building social support networks.
- K. The client's ability to adhere to treatment is assessed before starting an antiretroviral regimen and a service plan to address barriers is created.
- L. Prompt, frequent, and intensive follow-up is provided for clients during the first 4 to 6 weeks after beginning ART. Clients should be seen or contacted within 24 to 48 hours of beginning therapy to assess adherence and adverse effects. Additional follow-up 5 to 14 days after starting a new regimen is recommended to reinforce adherence and manage adverse effects. Some clients only need reassurance that adverse effects will pass, and others may need specific treatment. Individuals with time-limited adverse effects may need close personal follow-up to encourage them to continue treatment until the adverse effects pass. For clients whose schedules preclude visits, telephone contact can improve adherence and clinical outcomes. Frequency of contacts will vary based upon challenges faced by the client.
- M. Every interaction with a client was used as an opportunity to evaluate and reinforce adherence. Focus on adherence early in therapy as well as later when patients may develop "pill fatigue." Inquiries about adherence should be in an open and nonjudgmental fashion such as, "I know that taking all of these medications is hard. There can be so many side effects,

and it often gets in the way of your day. Are there times when you find it hard to take your medications?" Begin by asking open-ended questions. Then ask more detailed questions about timing of doses, numbers of pills, and impediments to taking medications. The answers elicited can help treatment adherence counselors, clinicians and patients/clients strategize ways to remove barriers to adherence in daily life.

- N. Treatment adherence counselors used tools to assist clients to become familiar with their medications, including: charts with pictures of pill; personalized schedules of medications to be taken at each time of day, illustrated with pictures, generic and brand names, and anticipated side-effects, as well as common adverse effects; 7-day pill boxes; and calendar /journals for keeping appointments and tracking lab values for viral load and CD4+ cells.
- O. HIV-infected individuals are seen regularly by their health care provider and all decisions regarding antiretroviral therapy are made by clinicians with expertise in HIV care.
- P. Relationship building between the health care provider and client is facilitated through the preparation of questions and concerns for the medical visit. Sometimes the treatment adherence counselor may need to accompany the client on the medical visit.

#### **STANDARD 2.4: OUTCOMES AND MEASURES FOR PROGRAMS**

Successful programs measure client adherence to ART. The effectiveness of the treatment adherence program is measured by:

- A. Client satisfaction surveys.
- B. The percent of people engaged in services that are initially assessed as marginally in care, not in care or not adherent to treatment.
- C. The percentage of clients who are in care as defined by HRSA.

### **STANDARD 3. OUTREACH AND REFERRAL**

More than 50% of people diagnosed with HIV are either marginally in care, have fallen out of care, or have never accessed care after diagnosis. The following are standards will help community based social service organizations support access and adherence to care.

#### **STANDARD 3.1: OUTREACH STRATEGIES**

- A. Strategies and methodologies meet diverse population needs. Some special populations include women, IDUs, offenders and ex-offenders re-entering the community, men-who-have-sex with men (MSM),

youth, African American, Latino, and transgendered individuals.

- B. Outreach efforts work closely with Counseling and Testing Referral (CTR) programs to get people into care within the first 3 months of their diagnosis.
- C. Treatment adherence counselors partner with existing clients to identify HIV+ individuals not in care within the client's social network.
- D. General marketing campaigns that advertise the benefits of early diagnosis and care are funded in high incidence regions. Venues for marketing include street signage, faith based organizations, all Ryan White funded program sites, STD clinics, CTR sites, health fairs, and drug and alcohol treatment programs.
- E. Community education forums on care and treatment for HIV can serve as an initial point of entry to care services. Regular forum participants are encouraged to bring HIV+, at risk, and affected friends and family to such forums.
- F. Treatment adherence counselors work with health care clinics to identify patients in need of adherence counseling and support.
- G. Referrals and referral tracking systems are established, including participation in any statewide client database for HIV services that might be established.

### **STANDARD 3.2: OUTCOMES AND MEASURES FOR OUTREACH**

The effectiveness of the treatment adherence outreach and referral activities are measured by:

- A. The percent of people identified and referred to treatment adherence services that are initially assessed as marginally in care, not in care or not adherent to treatment;
- B. The degree to which percentages of diverse populations are engaged in services reflects the regional epidemic demographics as identified by the CDC and NJDHSS.

### **STANDARD 4. INDIVIDUAL CLIENT SUPPORT: ENVIRONMENTAL AND SOCIAL FACTORS**

Clients' environmental resources include social support, financial assets, and basic resources such as food, clothing, shelter, and transportation. Unstable or lack of environmental resources creates a barrier to adherence. The following are programmatic standards for ways a community based social service organization can address client environmental and social needs.

#### **STANDARD 4.1: PROGRAM ELEMENTS**

- A. A thorough assessment of all clients' environmental and social support resources is conducted periodically as part of the client health outcomes assessment.

- B. Resolution of any environmental or social support barriers which negatively impact care (defined by HRSA) and treatment is facilitated through referral and collaboration with community resources (Ryan White funded and other). Any service gaps are documented and referrals are tracked.

### **STANDARD 4.2: OUTCOMES AND MEASURES FOR PROGRAM ELEMENTS**

The effectiveness of the interventions to resolve environmental and social support barriers to care and treatment are measured by:

- A. Client satisfaction surveys;
- B. The percent of people engaged in services that are initially assessed as marginally in care, not in care or not adherent to treatment due to environmental or social support barriers;
- C. Successful client access to referral services and resolution of environmental and social support barriers;
- D. Documented collaborations between service providers (i.e. letters of agreement, memoranda of agreement, memoranda of understanding, linkage agreements, subcontracts, or other formal agreements);
- E. The percent of clients who are in care as defined by HRSA.

### **STANDARD 5. INDIVIDUAL CLIENT SUPPORT: PSYCHOLOGICAL AND PERSONALITY FACTORS**

Psychological instability is a common barrier to care as defined by HRSA (viral load and CD4+ measures). Evaluation and treatment promotes stability in clients' lives and therefore successful health outcomes. The following are programmatic recommendations for ways in which community based social service organizations can address client psychological and personality related needs.

#### **STANDARD 5.1: PROGRAM ELEMENTS**

- A. The treatment adherence counselor consulted with and made an appropriate mental health referral when psychological instability was suspected as a barrier to care.
- B. The treatment adherence counselor worked collaboratively with the mental health or addictions professional to support access and adherence to care and treatment.
- C. Any unmet mental health and addictions service needs were documented and referrals were tracked.

## STANDARD 5.2: OUTCOMES AND MEASURES FOR INDIVIDUAL CLIENT SUPPORT

The effectiveness of the interventions to resolve psychological and personality factors that may be a barrier to successful health care access and adherence are measured by:

- A. Client satisfaction surveys;
- B. The percent of people engaged in services that are initially assessed as marginally in care, not in care or not adherent to treatment due to psychological and personality factors; percentages should reflect epidemiological data that notes the high incidence of depression, addiction and other mental health factors of people living with HIV;
- C. Percentage of clients utilizing active coping strategies such as to seek and obtain social or professional support during periods of distress, and developing problem-solving and decision-making skills;
- D. Documented collaborations between service providers (i.e. letters of agreement, memoranda of agreement, memoranda of understanding, linkage agreements, subcontracts, or other formal agreements);
- E. The percent of clients who are in care as defined by HRSA.

## STANDARD 6. EDUCATION PROGRAMS

Treatment education is vitally important to help clients understand their treatment regimen and the importance of adherence. Clients who understand the risks, benefits, effectiveness, and rationale of complex treatments are more likely to adhere to treatment. Understanding HIV disease and treatment can motivate individuals to stay healthy and make better choices about lifestyle and health care needs. A body of HIV-specific knowledge should be taught to clients before beginning therapy. The following are programmatic standards that community based social service organizations can use to address client HIV educational needs.

### STANDARD 6.1: EDUCATIONAL OPPORTUNITIES FOR PROVIDERS AND CLIENTS

- A. On-going educational programming is available for staff and clients such as conferences, teleconferences, community treatment education forums, small group education, individual face-to-face sessions, Internet access, treatment newsletters and fact-sheets to ensure all are up-to-date on HIV disease management.
- B. A body of HIV-specific knowledge is taught to clients before beginning therapy. Clients who understand the risks, benefits, effectiveness, and rationale of complex treatments are more likely to adhere. Minimally, the client should understand the following:
  - i. How HIV is transmitted;

- ii. How HIV replicates and weakens the immune system;
- iii. The common laboratory tests appropriate to their care, such as:
  - a. How immunosuppression is gauged by the degree of CD4+ cell depletion;
  - b. How the rate of disease progression can be gauged by the viral load and CD4+ cell count;
  - c. The effect of antiretroviral therapy on viral load, CD4+ cells, and therefore disease progression and survival;
- iv. The need to have laboratory tests done on time, and the time necessary for the tests to be processed by the laboratory;
- v. The need for 100% medication adherence;
- vi. The fact that minor lapses in adherence can lead to the emergence of drug resistance mutations that may cause the current regimen to fail, and limit future treatment options;
- vii. That many adverse effects of medication are time-limited and manageable;
- viii. What to do if they miss a dose or cannot access medication;
- ix. How to obtain medications if the pharmacy or the health care professional on call will not provide a refill;
- x. Secondary prevention for HIV, STDs and OIs;
- xi. Local social service system and resources.
- C. Client treatment service plans include educational goals.
- D. Educational materials are culturally competent, appropriate to literacy level, and offered in the dominant language(s) of the client.
- E. Educational methods used adult learning principles and methods.

### STANDARD 6.2: OUTCOMES AND MEASURES FOR EDUCATION PROGRAMS

The effectiveness of educational programming for clients and providers is measured by:

- A. Participant evaluations of programs;
- B. Program summaries that minimally note program dates, topics, number of participants, and participant identification (clients and/or provider groups);
- C. Provider demonstration of competencies to assess client need for health care support and ability to make appropriate and successful referrals.



## ACKNOWLEDGMENTS, REFERENCES AND INFORMATION SOURCES

Thanks to the other project participants: UMDNJ Center for Continuing and Outreach Education – Division of AIDS, and Coalition Members of the Statewide Coalition on Treatment Education and Advocacy.

The author presented the New Jersey Standards at *Elements of Success: An International Conference on Adherence to Antiretroviral Therapy*, December 2-4, 2004, Dallas, Texas.

### Footnotes

<sup>1</sup> [http://aidsinfo.nih.gov/guidelines/default\\_db2.asp?id=50](http://aidsinfo.nih.gov/guidelines/default_db2.asp?id=50)

<sup>2</sup> Center for AIDS Prevention Studies at the University of San Francisco, January 2003, Fact Sheet #46E.

<sup>3</sup> NPTEP, Howard University, et al, 2002

### Print Resources

1. *Elements of Success in HIV Clinical Care: Multiple Interventions That Promote Adherence*, Gary S. Reiter, MD, et al; *Topics in HIV Medicine*, Volume 8, Issue 5: August 2000. IAS-USA;
2. Margaret Chesney, PhD; Center for AIDS Prevention Studies, UCSF, *The Challenge of Adherence*, 12<sup>th</sup> World AIDS Conference, Geneva Switzerland, 1998;
3. Center for AIDS Prevention Studies at the University of San Francisco, January 2003, *Fact Sheet #46E; Determinants of entering HIV care: Preliminary data from the Antiretroviral Treatment Access Studies (ARTAS)*, Z Gaul, MSPH, et al, 2003

### Additional Resources

Other resources used in developing the Community Treatment Adherence Standards included websites of several national HIV/AIDS treatment information and advocacy organizations; experiences of the coalition members and their staff; the National Peer Treatment Education Project (NPTEP), and experiences of the participants of the *Statewide Conference on Treatment Education and Adherence* (June 2004, Princeton).

## THE NIMH AND IAPAC INTERNATIONAL HIV ADHERENCE CONFERENCE 2006

### JERSEY CITY, NJ, MARCH 8-10, 2006

A continuation of the Elements of Success International HIV Adherence Conference will be held at the Hyatt Regency on the Hudson in Jersey City, NJ, March 8-10, 2006. This conference is a unique opportunity for providers of HIV/AIDS care and treatment to translate up-to-date adherence research into practice! The conference includes plenaries featuring clinicians who are using novel models of HIV adherence, as well as presentations by the top HIV Adherence researchers from around the world.

This year, the conference is jointly sponsored by the International Association of Physicians in AIDS Care and the University of Medicine and Dentistry of New Jersey. The major supporter is the National Institute of Mental Health at the National Institutes of Health. You may register for the conference at: [www.peopleware.net/0646a](http://www.peopleware.net/0646a). To ensure that you are included on the mailing list, please send an email to David Rosen: [rosendv@umdnj.edu](mailto:rosendv@umdnj.edu). Include the phrase "Adherence Conference 2006" in the subject line, and, if you would like a brochure or call for abstracts mailed to you via USPS, include your address in the email body. Otherwise, you will receive your communication electronically.

### Reference note to Director's Message, Page 1

#### Ryan White funding is currently allocated within five distinct Titles:

- Title I: Emergency assistance to localities that are disproportionately affected by the AIDS epidemic
- Title II: State Health Departments to improve the quality, availability and organization of health care and support services for PLWHA and their families, especially Women, Infants & Children and special HIV health services programs, such as Special Projects of National Significance (SPNS), the AIDS Drug Distribution Program (ADDP) and Consortia
- Title III [b]: Health services organizations such as Community and Migrant Health Centers to support early intervention services
- Title IV: Health services organizations to provide clinical research on therapies for pediatric patients and women living with HIV/AIDS, and health care to pediatric patients and their families.
- Part F: Regionally based AIDS Education & Training Centers (AETCs) to train health care personnel in the diagnosis, treatment, and prevention of HIV infection. Part F also includes the dental reimbursement program run by dental schools.

# COMMUNITY BASED HIV TREATMENT ADHERENCE SUPPORT; NEW JERSEY STANDARDS OF PRACTICE

Questions refer to the content of the article and the notes that follow. To receive CME credit: complete exam, registration, and evaluation forms on-line at <http://ccoe.umdj.edu/aids> or fill in the forms on the next 2 pages, and mail or fax to UMDNJ-CCOE.

1. Which of the following is **not** described in the New Jersey Standards of Practice for HIV Treatment Adherence Support as a strategy for supporting patient adherence to HIV treatment?
  - a. Collaborations between health care providers and community based social service providers
  - b. Assessment of barriers to adherence by health care providers prior to beginning treatment
  - c. Requirement that all clients on ART participate in case management and support groups
  - d. Availability of mental health services for patients experiencing psychological instability
2. Patient education program objectives should include:
  - a. An understanding of HIV pathogenesis
  - b. Knowledge of local resources
  - c. Comprehension of how ART effects viral replication
  - d. All of the above
3. An assessment of patient environmental factors includes:
  - a. Stable housing
  - b. Nutritional resources
  - c. Income and other financial resources
  - d. All of the above
4. Patient psychological factors that can influence treatment adherence are:
  - a. Substance abuse and addiction
  - b. Depression
  - c. Social support
  - d. All of the above
5. Which of the following is a recommended strategy for improving adherence to ART?
  - a. Social marketing campaigns on the success of Antiretroviral Therapy (ART)
  - b. Provision of ART at first medical visit following HIV diagnosis
  - c. Follow-up by medical and/or treatment adherence staff within 48 hours of beginning ART or a new regimen
  - d. Incentive programs that offer food vouchers, etc.
6. Outcomes for effectiveness of treatment adherence staff include:
  - a. Percentage of clients with undetectable viral load
  - b. Percentage of clients retained in treatment adherence counseling
  - c. Percentage of clients who are in HIV care
  - d. Both b and c
7. Which of the following outreach strategies help community organizations support access and adherence to care and treatment?
  - a. Working closely with counseling testing & referral (CTR) programs
  - b. Home visits in high incidence areas
  - c. Targeted marketing campaigns that advertise benefits of early diagnosis and treatment
  - d. Both a and c
8. The HIV-positive person will be most likely to be adherent to an antiretroviral regimen if he or she:
  - a. Is employed full-time
  - b. Feels comfortable taking medications in front of others
  - c. Has private insurance
  - d. Is newly diagnosed with HIV
9. The primary goal of clinic and social service based treatment adherence support programs is to:
  - a. Ensure that at least 50% of clients are initiated on ART (antiretroviral therapy)
  - b. Provide comprehensive on-site services for substance use and mental health treatment to support clients
  - c. Increase the proportion of people living with HIV who are linked to appropriate care and treatment services
  - d. Maintain >95% adherence rates for all clients taking ART
10. New Jersey Standards of Practice for HIV Treatment Adherence Support include:
  - a. Guidance for physicians on recommended ART regimens
  - b. Specific program intervention strategies for MSM, African American, and transgendered individuals
  - c. Measurable outcomes for adherence support staffing, program effectiveness, outreach, client supportive services, and client education
  - d. All of the above

**University of Medicine and Dentistry of New Jersey  
Center for Continuing and Outreach Education**

**COMMUNITY BASED HIV TREATMENT ADHERENCE SUPPORT; NEW JERSEY STANDARDS OF PRACTICE**

*Registration Form*

In order to obtain AMA PRA category 1 credit, participants are required to:

- (1) Read the learning objectives, and review the activity, and complete the self-assessment.
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**SELF-ASSESSMENT TEST**

Circle the best answer for each question on page 10.

- |            |            |             |
|------------|------------|-------------|
| 1. A B C D | 4. A B C D | 7. A B C D  |
| 2. A B C D | 5. A B C D | 8. A B C D  |
| 3. A B C D | 6. A B C D | 9. A B C D  |
|            |            | 10. A B C D |

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University of Medicine and Dentistry of New Jersey

Center for Continuing and Outreach Education

COMMUNITY BASED HIV TREATMENT ADHERENCE SUPPORT; NEW JERSEY STANDARDS OF PRACTICE

Activity Evaluation Form

The planning and execution of useful and educationally sound continuing education activities are guided in large part by input from participants. To assist us in evaluating the effectiveness of this activity and to make recommendations for future educational offerings, please take a few moments to complete this evaluation form. Your response will help ensure that future programs are informative and meet the educational needs of all participants. Please note: CE credit letters and long-term credit retention information will only be issued upon receipt of this completed evaluation form. Thank you for your cooperation!

PROGRAM OBJECTIVES: Having completed this activity, are you better able to:	Strongly Agree		Strongly Disagree	
Objective 1: <b>Explain</b> the roles of the patient, the clinician, the health care program, and the regimen in supporting or creating obstacles to adherence.	5	4	3	2 1
Objective 2: <b>Recognize</b> reliable and unreliable predictors of adherence	5	4	3	2 1
Objective 3: <b>Identify</b> strategies to improve treatment adherence that are related to each element of treatment adherence	5	4	3	2 1

OVERALL EVALUATION:	Strongly Agree		Strongly Disagree	
The information presented increased my awareness/understanding of the subject.	5	4	3	2 1
The information presented will influence how I practice.	5	4	3	2 1
The information presented will help me improve patient care.	5	4	3	2 1
The faculty demonstrated current knowledge of the subject.	5	4	3	2 1
The program was educationally sound and scientifically balanced.	5	4	3	2 1
The program avoided commercial bias or influence.	5	4	3	2 1
Overall, the program met my expectations.	5	4	3	2 1
I would recommend this program to my colleagues.	5	4	3	2 1

If you anticipate changing one or more aspects of your practice as a result of your participation in this activity, please provide us with a brief description of how you plan to do so.

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Please provide any additional comments pertaining to this activity (positives and negatives) and suggestions for improvement:

Please list any topics that you would like to be addressed in future educational activities:

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CE Activity Code: o6HCo6-DEo1





Stephen M. Smith, MD

## NEW YORK CITY HIV SUPERBUG: FEAR OR FEAR NOT?

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*This article was previously published 2 March 2005, online in Retrovirology 2005, 2:14 doi:10.1186/1742-4690-2-14; at: <http://www.retrovirology.com/content/2/1/14>*

### ABSTRACT:

On February 11, 2005, the New York City Department of Health and Mental Hygiene announced that a city resident had recently been infected with a multi-drug resistant form of HIV and rapidly progressed to AIDS. The Health Commissioner, Thomas R. Frieden, called for increased vigilance against this new strain. Is this situation an emerging crisis or simply an unusual case report of rapid HIV progression?

On February 11, 2005, New York City (NYC) health officials announced the discovery of a “rare strain of multi-drug resistant HIV that rapidly progresses to AIDS.” According to the NYC Department of Health and Mental Hygiene, a man in his mid-40s was diagnosed with HIV infection in December 2004. Shortly after his diagnosis, testing, at the Aaron Diamond AIDS Research Center in Manhattan, revealed that his virus was resistant to almost all anti-HIV therapeutics. Further, despite being infected for only 2–20 months, the man had developed AIDS. NYC Health Commissioner Thomas R. Frieden, MD, MPH, stated, “This case is a wake-up call. First, it’s a wake-up call to men who have sex with men, particularly those who may use crystal methamphetamine...now, we’ve identified this strain of HIV that is difficult or impossible to treat and which appears to progress rapidly to AIDS.” Dr. Frieden called on this community to help stop the spread of this and other drug resistant strains of HIV. He also called on NYC doctors and the public health system to improve HIV prevention counseling, to perform HIV drug resistance testing among treatment naïve, HIV+ persons, and to improve anti-HIV drug adherence.

At the 12th Conference on Retroviruses and Opportunistic Infections (CROI) in Boston, Drs. David Ho and Martin Markowitz of the Aaron Diamond AIDS Research Center in Manhattan presented clinical and laboratory data regarding the NYC resident<sup>1</sup>. He had tested negatively for HIV-1 antibodies several times before and in May 2003. His total lymphocyte counts during these time points were repeatedly normal. Investigators believe that the NYC resident may have been infected in October 2004, when he, while on crystal methamphetamine, engaged in unprotected, receptive and insertive anal sex with multiple partners. In early November 2004, the NYC resident developed a febrile illness, and then in December 2004, he tested positive for antibodies against HIV. His personal physician, concerned over the possibility of recent acute HIV-1 infection, referred the NYC resident to Dr. Martin Markowitz. At the time of diagnosis, his CD4+ T-cell count was 80 cells/mm<sup>3</sup> and it has since fallen to less than 50. The NYC resident meets one criterion for the diagnosis of AIDS; his CD4+ T-cell count is less than 200 cells/mm<sup>3</sup>. His viral load has varied from ~100 K to 650 K/ml. The NYC resident’s virus was tested and found to be resistant to all but two anti-HIV drugs, efavirenz



(Sustiva®) and enfuvirtide (Fuzeon®; T20). This high degree of drug resistance existed before the NYC resident was treated with any anti-HIV compound.

Is this case a harbinger of a new epidemic with this superbug or is it just an isolated, forme fruste of HIV infection? No one knows the answer to this question yet, but we do have plenty of data to suggest that the latter is the case. In people naïve to drug therapy, bone fide antiviral resistance is uncommon. A recent USA based study of treatment-naïve patients found that the prevalence of mutations associated with drug resistance was 8.8%<sup>2</sup>. This means 8.8% of the subjects' viruses tested positive by genotyping for 1 or more mutations associated with drug resistance. Having a single mutation associated with resistance does not necessarily make a virus drug resistant. For many drugs, HIV must contain several mutations to become resistant. This fact is true for most protease inhibitors (PIs) and for several nucleoside analogue reverse transcriptase inhibitors (NRTIs). Therefore, the overall level of drug resistance is well less than 8.8% reported in this study. Indeed, in this study, no significant resistance to protease inhibitors was seen. A similar study found the overall prevalence of drug resistance mutations was 8.3%, as also determined by genotyping<sup>3</sup>. However, when viruses containing these mutations were analyzed by phenotyping, only 39% demonstrated decreased reduced drug susceptibility. In other words, less than 3.5% of all isolates had phenotypic resistance.

A commonly held view on why the level of drug resistance is low is that most mutations associated with drug resistance, also decrease viral fitness. Except the K103N reverse transcriptase mutation, which

confers resistance to the three approved non-nucleoside inhibitors (NNRTIs), other mutations, associated with high level drug resistance, are thought to significantly decrease viral fitness. Theoretically, in the absence of drug pressure in a newly infected individual, wild-type virus is either selected for during transmission or the transmitted, resistant virus mutates back towards the fitter wild type. The current observation is that the vast majority of viruses in treatment-naïve patients are sensitive to almost all drugs.

In addition to CD4, the virus, isolated from the NYC resident, uses CXCR4 or CCR5 to enter cells<sup>1</sup>. Such viruses, termed dual-tropic, are rarely seen in newly infected individuals. Typically, an R5 virus, which utilize CCR5, is the transmitted type. After years of infection, in approximately 50% of individuals, the viruses' tropism changes from CCR5 to CXCR4<sup>4</sup>. This phenotypic change is associated with an accelerated disease course. People, who are homozygous for the CCR5, 32-bp deletion, do not express functional CCR5 and have a high relative resistance to infection with HIV. In those  $\Delta 32$  homozygotes, who have become infected with HIV (8 individuals reported), the disease course appears to be more rapid<sup>5</sup>. Most of these individuals had CD4+ T-cell counts less than 300 cells/mm<sup>3</sup> at the time of diagnosis. It is unclear why these individuals became infected, while the vast majority of  $\Delta 32$  homozygotes remain uninfected. Possibly, these 8 individuals have some other aberration, which allows them to become infected with an X4 virus and, in turn, leads to an accelerated disease course. Perhaps, the NYC resident has a similar abnormality, which has lead to an increased rate of CD4+ T-cell depletion.

Also at CROI this year, Drs. Stephen Gange and Alvarez Munoz from Johns Hopkins University Bloomberg School of Public Health presented models of rapid HIV progression probability, based on two, large prospective cohorts<sup>6</sup>. These studies, the MACS and the WIHS, have been on-going for the past 21 and 11 years respectively and have collected longitudinal data on 391 seroconverters. In the pre-HAART era, the median time to AIDS was 8.3 years. Using the cohorts' data, Drs. Gange and Munoz estimated the probability of clinical AIDS developing within 6–24 months or a low CD4+ T-cell count existing at the first visit after diagnosis (within the first 9 months of infection). Their model predicts that 7 in 10,000 patients develop clinical AIDS within 6 months of infection. This number increases to 45 in 10,000 after 12 months. Similarly, 10 in 10,000 HIV infected individuals have a CD4+ T-cell count less than 200 cells/mm<sup>3</sup> after 4.5–9 months of infection.

Several reports of rapidly progressing HIV infection have been published. The rapid disease course of the NYC resident is rare, but hardly unique. To date, no cluster of rapid progressors has been described. All rapid progressors have been unrelated, either genetically or virologically. While multi-drug resistant (MDR) viruses may be overall less fit compared with wild-type, drug sensitive strains, MDR HIV still causes steady CD4+ T-cell depletion. Therefore, it is highly probable that the NYC resident has a genetic predisposition, which led to rapid progression, rather than a new strain of HIV-1, which is simultaneously super-aggressive and multi-drug resistant.

Our experience at a large, inner city HIV clinic is in agreement with the above data. We do not see rapidly progressing,

newly diagnosed individuals. We also do not see MDR HIV in our treatment-naïve patients. Review of our data does not reveal any evidence of MDR virus in persons, who have never been on therapy.

To determine whether this “superbug” has spread to others, the NYC Department of Health is appropriately and aggressively investigating the sexual contacts of the NYC resident. The reason for the NYC Department of Health press release at this early point in the investigation is unclear. In the absence of a documented cluster of patients, should the entire health system react? No, we should wait for more information. I do agree that genotypic resistance testing for treatment-naïve HIV+ patients is prudent, especially when the person is thought to have been infected within the past year. Of course, most patients do not know when they were infected, so we are testing each new patient.

Given the availability of free, rapid testing for HIV in New Jersey, we are strongly encouraging any one with current or previous high-risk behavior to get tested and determine his/her HIV status. The best way to fight this disease is with knowledge: knowledge on one's infection status, knowledge on how to avoid becoming infected, and knowledge on how not to infect some one else. HIV is not the common cold. It is transmitted through well-described behaviors, predominantly sex, especially receptive anal intercourse, and intravenous drug use with shared needles. These behaviors can be modified to reduce or eliminate the risk of contracting HIV. Two recent studies conclude that universal testing for HIV is a cost effective way to combat this infection in the USA <sup>7-9</sup>. Outreach prevention education and widespread testing are probably more effective public health strategies than sensational press releases. Dr. Frieden's call for increased vigilance against drug resistant HIV implies that regular, old-fashioned HIV infection is not horrific enough. Any one who has seen this disease up close knows that is not the case. While we have partially effective therapies and we better understand its pathogenesis, HIV infection in this country, not as life threatening as it once was, remains quite life altering.

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### NEW JERSEY AIDSLINE

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## IN THE NEWS!

### Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents

April 7, 2005

The Antiretroviral treatment guidelines were updated on April 07, 2005, by the Panel on Clinical Practices for Treatment of HIV Infection convened by the Department of Health and Human Services (DHHS) [http://www.aidsinfo.nih.gov/guidelines/adult/AA\\_040705.pdf](http://www.aidsinfo.nih.gov/guidelines/adult/AA_040705.pdf) (summary of changes below).

#### WHAT'S NEW IN THE DOCUMENT?

The following changes have been made to the October 29, 2004 version of the guidelines:

1. New recommendations for initiation of NNRTI therapy - based on increased risk of symptomatic hepatotoxicity when nevirapine is initiated in men and women with high CD4+ T cell counts:
  - Nevirapine-based regimens are recommended as alternatives for adult females with CD4+ T cell counts <250 cells/mm<sup>3</sup> and adult males with CD4+ T cell counts <400 cells/mm<sup>3</sup>. (BII)
  - The Panel does not recommend initiation of nevirapine in adult females with CD4+ T cell counts >250 cells/mm<sup>3</sup> and adult males with CD4+ T cell counts >400 cells/mm<sup>3</sup> unless the benefit clearly outweighs the risk. (DI)
2. Removal of prior recommendation for the use of rifampin with ritonavir-boosted saquinavir - based on reports of significant elevation (up to 20 x upper limit of normal) of serum transaminases in a Phase I study evaluating the pharmacokinetic interaction of this drug combination in healthy volunteers. (see FDA news at right)
3. Revision of Tables 28 and 29 (per Perinatal Guidelines) to reflect the recent FDA labeling change for efavirenz from Pregnancy Category C to Category D.
4. Addition of a table entitled "Antiretroviral Agent Available Through Expanded Access Program." [Tipranavir]
5. Revision of Table 19 to reflect the FDA labeling change for ritonavir and lopinavir/ritonavir listing new warnings and contraindications.

### FDA WARNING on Rifampin-Ritonavir

The following warning will affect HIV infected persons with TB and will also affect the selection of postexposure prophylaxis for invasive *Neisseria meningitis* for HIV infected persons.

#### **Rifampin Plus Ritonavir-Boosted Saquinavir Therapy Linked to High Risk of Hepatotoxicity.**

Feb. 10, 2005 — The U.S. Food and Drug Administration (FDA) and Roche Laboratories, Inc., have warned healthcare professionals via letter that use of rifampin is contraindicated in HIV-infected patients receiving ritonavir-boosted saquinavir/saquinavirmesylate (Fortovase/Invirase) as part of combination antiretroviral therapy (ART) due to a high risk of hepatotoxicity.

Roche and FDA notified healthcare professionals about an important drug interaction warning. Drug-induced hepatitis with marked transaminase elevations has been observed in healthy volunteers receiving rifampin 600 mg once daily in combination with ritonavir 100 mg/saquinavir 1000 mg twice daily (ritonavir boosted saquinavir). Roche now advises prescribers that Rifampin should not be administered to patients also receiving saquinavir/ritonavir (ritonavir boosted saquinavir) as part of combination antiretroviral therapy (ART) for HIV infection. Alternatively, this information may be reported to the FDA's MedWatch program by phone at 1-800-FDA-1088, by fax at 1-800-FDA-0178, online at <http://www.fda.gov/medwatch>, or by mail to 5600 Fishers Lane, Rockville, MD 20852-9787. <http://www.fda.gov/medwatch/SAFETY/2005/safety05.htm#Invirase>

**Resource:** Subscribe (free) to FDA medical alert e-bulletin service <http://www.fda.gov/medwatch/elist.htm>.



## NON-OCCUPATIONAL POST-EXPOSURE PROPHYLAXIS: NEW CDC GUIDELINE RAISES QUESTIONS ABOUT IMPLEMENTATION

Kimi Nakata, MSW, MPH

The Centers for Disease Control and Prevention (CDC) issued guidelines on January 21, 2005, for the use of a post-exposure prophylaxis (PEP) antiretroviral drug regimen to prevent HIV infection after nonoccupational exposure to HIV through sexual intercourse, sexual assault, injection drug use or accidents.

This recommendation from the U.S. Department of Health and Human Services for Non-Occupational Post-Exposure Prophylaxis (nPEP) is based on more than six years of discussion and research following the CDC's 1998 statement on nonoccupational PEP in *Management of Possible Sexual, Injecting-Drug-Use, or Other Nonoccupational Exposure to HIV, Including Considerations Related to Antiretroviral Therapy: Public Health Service Statement*, MMWR 1998;47 (No. RR-17): pp. 1-17. The 1998 abstract summary stated: "Some healthcare providers have proposed offering antiretroviral drugs to persons with unanticipated sexual or injecting-drug-use HIV exposure to prevent transmission. However, because no data exist regarding the efficacy of this therapy for persons with nonoccupational HIV exposure, it should be considered an unproven clinical intervention."

Since that report, researchers have conducted animal and human studies of postexposure prophylaxis, including postnatal (mother-to-child) prophylaxis and occupational PEP, and clinicians have used PEP with patients presenting in emergency rooms, infectious disease and primary care practices. Study results have shown strong demonstration of the value of providing antiretroviral treatment as postexposure prophylaxis. The new report examines the risks and benefits of a 28-day regimen of antiretroviral treatment for individuals whose HIV status is not yet confirmed, and provides an algorithm [figure 1] to help clinicians assess the degree of risk of HIV exposure, to determine the appropriateness of nPEP. The guidelines report concludes:

Accumulated data from animal and human clinical and observational studies demonstrate that antiretroviral therapy initiated as soon as possible within 48–72 hours of sexual, injection-drug-use, and other substantial nonoccupational HIV exposure and continued for 28 days might reduce the likelihood of transmission. Because of these findings, DHHS recommends the prompt initiation of nPEP with HAART when persons seek care within 72 hours after exposure, the source is known to be HIV infected, and the exposure event presents a substantial risk for transmission. When the HIV status of the source is not known and the patient seeks care within 72 hours after exposure, DHHS does not recommend for or against nPEP but encourages clinicians and patients to weigh the risks and benefits on a case-by-case basis. [see figure 1]

The nPEP protocol is based on the research evidence showing that this antiretroviral treatment intervention is most effective within 24-72 hours of exposure, when it is most effective in interrupting transmission of HIV, through suppression of viral replication. The benefits of treatment must be balanced against the toxicity risks and expense of antiretroviral treatment. The CDC guidelines provide recommendations for several preferred three-drug regimens. If the source of the exposure is known and willing to provide HIV status and resistance testing results, then the nPEP protocol can be tailored to avoid resistance.

The guidelines were met with a mixed reaction in medical journals, newspaper articles, and brief interviews with several New Jersey clinicians. The positive remarks supported nPEP as an advance in providing intervention to reduce HIV infection for individuals at the highest risk. Their concerns focused on anticipated difficulties in providing assessment and antiretroviral treatment in overburdened, understaffed emergency rooms and private offices of physicians

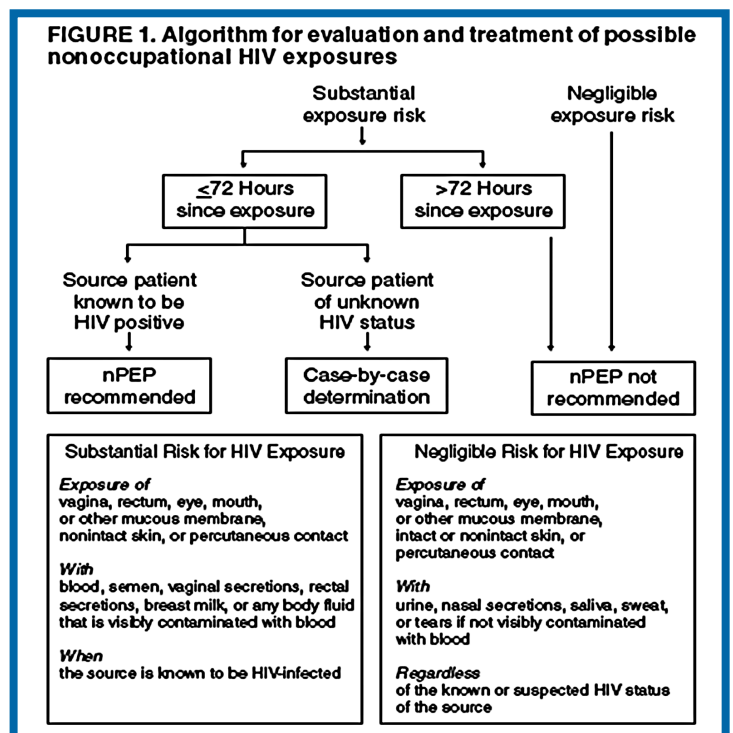


Figure 1: Centers for Disease Control and Prevention, MMWR Recommendations Rep. 2005; 54 (RR-2): 1-20

who might not be familiar with HIV treatment protocols. The clinicians identified several areas in which they have begun to develop protocols and responses, but feel that much further work is needed both in the field and in research, to make nPEP a consistent, accessible, effective intervention.

1. PEP interventions have been offered to sexual assault victims for many years, but there is little research to show its extent and effects. Post-assault protocols in the Emergency Departments include screening for HIV, Hepatitis B, Hepatitis C, pregnancy, and syphilis, with empiric treatment for pregnancy and gonorrhea. Follow-up protocols include counseling and legal referrals, but emergency departments usually refer patients to their own physicians or infectious disease clinics for follow-up medical care. Several sites report that they have begun or are developing collaborations between infectious disease and emergency departments to improve continuity of care and assure that patients are linked to providers who are knowledgeable about antiretroviral treatment.

2. Publicizing and providing nPEP may give a message that unprotected sexual activity and needle-sharing are less risky for acquiring HIV infection, now that there is a “morning after” treatment. Some sites limit or plan to limit nPEP to one series, or to one per year, and will focus on rapid HIV testing and counseling as the most realistic intervention for these patients.

3. Antiretroviral medication regimens are demanding for patients, both because they require adherence to specific schedules and multiple pills, and because side effects are most common in the first few weeks of treatment. Medical follow-up services would improve adherence and adjustment in regimens if necessary.

4. The cost of nPEP will probably not be covered by most private or public health insurance programs, and emergency department budgets would be quickly strained by the costs of testing and medications. Medication costs alone may range from \$600-\$1,200 for a 28-day regimen. Resistance testing, recommended when patients identify a known HIV-positive person who may have resistant virus, is also expensive and may not be covered by insurance (see #7).

5. Primary care physicians, emergency department clinicians, and others who care for patients reporting a possible HIV exposure will need training in evaluation for possible nPEP, and use of antiretroviral medications including the nPEP regimens. Collaborations, as noted above, may include consultation with infectious disease specialists that can improve the provision of appropriate care by emergency departments and primary care providers.

6. The clinical provider or team providing nPEP is expected to follow the CDC’s guidelines for monitoring, or to link patients with an infectious disease clinic or physician for follow-up. They should also assure that the patient is offered counseling on HIV prevention, care, and the nPEP regimen including toxicity concerns. The recommended schedule for evaluation, care, and follow-up indicates intervals of baseline, 3-5 days later for counseling about lab results and assessment of medication side-effects and adherence, followed by testing and assessment at 4-6 weeks, 3 months, and 6 months after exposure. Additional funding and staffing may be needed to provide these counseling, outreach, medical, and laboratory services.

7. Provision of nPEP may lead to increased resistance to HAART medications, as individuals take HAART briefly. A patient receiving nPEP may have been infected by a “source patient” with resistance to one or more antiretroviral medication classes, but this information may not be available before nPEP is prescribed. Collaboration between providers, and skilled patient interviewing, may help reduce this problem.

#### References:

CDC: nPEP Guidelines (2005)

Centers for Disease Control and Prevention. *Antiretroviral postexposure prophylaxis after sexual, injection-drug use, or other nonoccupational exposure to HIV in the United States: recommendations from the U.S. Department of Health and Human Services*. MMWR 2005;54(No. RR-2). Available online at: <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5402a1.htm>

CDC: Occupational PEP Guidelines (2001)

Centers for Disease Control and Prevention. *Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HCV and HIV and Recommendations for Postexposure Prophylaxis*. MMWR June 29, 2001. Available online at: <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5011a1.htm>

National AETC Resource Center

Postexposure Prevention section includes links to guidelines, clinician tools, slidesets, and patient materials as well as a link to free online CME. <http://www.aidsetc.org/aidsetc?page=et-30-26&catid=pep&=1>

NYSDOH – AIDS Institute

HIV Post-Exposure Prophylaxis Following Non-Occupational Exposure Including Sexual Assault  
Updated December 2004:  
[http://www.hivguidelines.org/public\\_html/npep/npep.pdf](http://www.hivguidelines.org/public_html/npep/npep.pdf)

New Mexico AIDS Info Net fact sheets (Patient Information)

#156: Treatment After Exposure to HIV and #103: Acute HIV Infection  
Available in English and Spanish, and in Adobe PDF and Microsoft Word formats. Source: Mountain-Plains AETC  
<http://www.aidsinonet.org/topics.php>

## INTERNET RESOURCES

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### UMDNJ - CENTER FOR CONTINUING AND OUTREACH EDUCATION - DIVISION OF AIDS EDUCATION

[ccoe.umdj.edu/aids](http://ccoe.umdj.edu/aids)

Training programs for HIV/AIDS health and social service professionals. You can register online for most UMDNJ HIV/AIDS continuing education courses at:

[www.peopleware.net/o646a](http://www.peopleware.net/o646a)

Online CME is accessible free. Current HIV publications include: Opportunistic Infections in HIV/AIDS (New Jersey Medicine, November 2004); Rapid Diagnostic Testing for HIV and Impact of the New Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents (New Jersey AIDSline, Winter 2004-05)

<http://ccoe.umdj.edu/online/index>

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### NJDHSS-DHAS WEBSITE

[www.state.nj.us/health/aids/  
rapidtesting/index.shtml](http://www.state.nj.us/health/aids/rapidtesting/index.shtml)

New Jersey state rapid testing site! FAQs, locations, and articles.

[www.state.nj.us/health/aids/aidsprv.htm](http://www.state.nj.us/health/aids/aidsprv.htm)

Epidemiological reports, policies, and clinical guidelines for HIV/AIDS care and services in New Jersey. Free CME articles.

[www.state.nj.us/health/aids/aidsqtr.htm](http://www.state.nj.us/health/aids/aidsqtr.htm)

New Jersey HIV/AIDS Semi-annual Newsletter (statistical report).

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### AETC NATIONAL RESOURCE CENTER

[www.aids-etc.org](http://www.aids-etc.org)

HIV treatment guidelines and key journal articles and news releases, links to all AIDS Education and Training Centers, training materials and curricula, and evaluation tools.

### US DEPT. OF HEALTH & HUMAN SERVICES

[www.aidsinfo.nih.gov](http://www.aidsinfo.nih.gov)

A service of the US Department of Health and Human Services offering HIV/AIDS treatment guidelines, other information on prevention, treatment, and research.

<http://clinicaltrials.gov>

A service of the US National Institutes of Health

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### CDC-INFO

**CDC-INFO** (Formerly known as the CDC National AIDS Hotline)

1-800-CDC-INFO (1-800-232-4636)

1-888-232-6348 TTY

[cdcinfo@cdc.gov](mailto:cdcinfo@cdc.gov)

In English, en Español 24 Hours/Day

### CDC National Prevention Information Network (NPIN)

HIV and STD-related News summaries, funding announcements, materials, conference and satellite broadcast announcements.

<http://www.cdcpin.org>

# SAVE THE DATES!

## Save the Date

**November 3, 2005**

Reducing Perinatal HIV Transmission

(Princeton, NJ)

**November 15, 2005**

New Jersey Ryan White All-Titles conference

(Piscataway, NJ)

**March 8-10, 2006**

NIMH and IAPAC International HIV Adherence  
Conference 2006

(Jersey City, NJ)

For more information go to  
[ccoe.umdj.edu/aids](http://ccoe.umdj.edu/aids), or call  
973.972.3690.

To register, go to [www.peopleware.net/0646a](http://www.peopleware.net/0646a), or call 800.227.4852, option 3.

## HIV/AIDS Medical Update Series: Free On-site Training

### Topics available:

- Diagnosis and Initial Management of HIV/AIDS: What the Primary Care Physician Should Know
- HIV in Pregnancy - Preventing Perinatal Transmission
- HIV/AIDS and Hepatitis C Co-Infection
- Immunizations for HIV Positive Adults
- Prevention and Prophylaxis for Occupational Exposure to HIV and Other Blood Borne Pathogens
- Prophylaxis and Treatment of Opportunistic Infections in Patients with HIV Disease
- Rapid HIV Testing

This free series for physicians, nurses, and other health care professionals and paraprofessionals has been extended.

**Call or e-mail** to schedule a 1-hour HIV medical education program at your health care site, and to find out about obtaining continuing education credit. Complete a brief request form available from Deborah Bottinick at (609) 921-6622 or [dbottinick@academycme.org](mailto:dbottinick@academycme.org)

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